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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/238,405	05/05/94	CAPON	D CELL5.3

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EXAMINER	
HAYES, R	
ART UNIT	**PAPER NUMBER**
1647	44

DATE MAILED: 06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant
08/238,405	Capon et al
Examiner	**Art Unit**
Robert C. Hayes	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 4, 2001*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *57, 59, 64, 65, 67, and 69* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *57, 64, 65, 67, and 69* is/are rejected.

7) ☒ Claim(s) *59* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed 4/17/01 has been entered.

2. The addendum to Paper No. 43 (i.e., as it relates to the references, Goverman et al., and Weiss)/ information disclosure statement filed 4/17/01, fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office (i.e., PTO Form 1449). It has been placed in the application file, but the information referred to therein has not been considered.

3. The rejection of claims 57, 64, 67 & 69 under 35 U.S.C. 102(b) as being anticipated by Kuwana et al., is withdrawn because claim 57 has been amended to require cytoplasmic domains that no longer comprise only Kuwana's α and β chains.

4. Claim 59 stands objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Applicants' arguments filed 4/17/01 have been fully considered, but they were not deemed to be persuasive.

7. Claims 57, 64-65, 67 & 69 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper # 41, and as follows.

In contrast to Applicants' assertions on pages 4-5 of the response, the pending rejection is a new matter rejection under 35 USC 112, first paragraph, and not a rejection over the prior art reference, "Gross et al." Therefore, Applicants' arguments are moot.

Note that no where on page 7 of the specification is the "concept" of "transduces a signal... in the absence of a T-cell receptor" contemplated; thereby, constituting new matter (i.e., as it relates to base claim 57). Note again that no where on pages 30-31 of the specification is the *generic concept* of " transduces a signal... in the absence of a T-cell receptor" contemplated for a cytoplasmic domain that does not include the **ζ chain of the Fc receptor**; thereby, constituting new matter. In other words, the proper context contemplated in the specification is that only a chimeric protein comprising the **ζ chain of the Fc receptor** can "transduce a signal... [when] in the absence of a T-cell receptor", given a fair reading of the specification as previously made of record; thereby, still constituting new matter (especially as it relates to now amended claim 57,

which alternatively now recites broader concepts within a Markush group that do not require the **ζ chain of the Fc receptor**). Therefore, Applicants' discussion on page 5 of the response is moot, in which the mere mention of a η chain in the "Background" section of the specification cannot reasonably be extrapolated to constituting contemplation of a generic concept of "transduces a signal... *in the absence of a T-cell receptor*", and alternatively only clouds the pending issue of new matter.

Lastly, it is noted that Applicants ignored the Examiner's suggestion to incorporate claim 59 (versus claim 71) into independent claim 57, in order to obviate this rejection.

8. Claims 57, 64, 67 & 69 stand rejected under 35 U.S.C. 102(e) as being anticipated by Eshhar et al. (U.S. Patent 5,906,936), for the reasons made of record in Paper # 41, and as follows.

Applicants' argue on pages 6-8 that "Eshhar et al. is cumulative to Gross et al." However, Gross et al. has never been properly made of record, and therefore, Applicants' comments related to Gross are moot, which is further not part of the instant rejection. Secondly, although Applicants' assertions that MD.45 cells and Jurkat cells express T cell receptor are persuasive (e.g., see also column 3, lines 63-66, and column 9, line 1), the claims alternatively are directed toward "chimeric protein" products comprising a Markush group reciting CD3 zeta (ζ), eta (η), gamma (γ), delta (δ), epsilon (ϵ) chains and a tyrosine kinase, in which column 3, lines 6-

7 discloses that Eshhar's invention is directed toward using the "T-cell receptor (α, β, γ and δ chains)"; thereby, meeting the limitations of new claim 57.

Applicants then attempt to argue on page 7 of the response that "the γ and δ chains of Eshhar et al. are not the CD3 γ and δ chains of the instant invention". However, no where is any structure (i.e., SEQ ID NO) recited in the claims to distinguish use of Eshhar's γ and δ chains from that of the instant invention. Moreover, column 3, line 66 specifically states that "any other type of cell which expresses **CD3/TcR**" relates to Eshhar's invention; thereby, making Applicants' arguments moot (i.e., as it relates to Eshhar contemplating use of CD3 γ and δ chains).

In summary, Eshhar et al. teach a membrane bound chimeric Ab/T-cell receptor chimeric protein (i.e., a tyrosine kinase; as it relates to claim 57), which also can use T-cell receptor α, β, γ and δ chains (e.g., column 4, lines 6-7; as it relates to claim 57) in a construct by removing the TcR V domain and replacing it with an antigen binding domain from a single chain antibody V domain (e.g., columns 5-7, Figure 4; as it relates to claim 57). Eshhar's chimeric protein comprises a signal/leader sequence and an extracellular C region that is naturally joined to the transmembrane domain, as well as a cytoplasmic domain (e.g., column 6 & Figures 8-9), which transduces a signal, as evidenced by IL-2 production (e.g., column 10 & Figure 1; as it relates to claim 57). Transfection of this chimeric protein construct into mammalian/human Jurkat cells (e.g., column 8-9 & Figure 4), and into cytotoxic T lymphocytes, is then described (e.g., bottom of column 3); thereby, meeting the limitations of claims 64 & 67, in which neither of these cell

lines would be recognized as foreign in an appropriate host due to their inherent "non-MHC restricted manner" (e.g., see columns 11-12; as it relates to claim 69).

It is noted that the courts have held that:

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray,* 10 USPQ 2d 1922 (1989); *In re Best,* 195 USPQ 430 (CCPA 1976).

Further, the courts have held that "when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product..., a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable". *In re Brown*, 173 USPQ 685 (1972).

Lastly, it is noted that Applicants ignored the Examiner's suggestion to incorporate claim 59 (versus claim 71) into independent claim 57, in order to obviate this rejection.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
June 21, 2001

Gary L. Kunz
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